

# What pharmaceutical companies should know: Combining checkweighing with coding and verification for track and trace / serialization / ePedigree compliance

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## Key Words

Track and Trace, serialization, ePedigree, pharmaceutical products

## Objective

The objective of this white paper is to provide background to aid in understanding of serialization methodologies for pharmaceutical products. Because the topic is extremely broad, this paper will focus specifically on how checkweighers can play a significant role in meeting track and trace requirements for package components.

## Track and trace becoming reality

The U.S. Food and Drug Administration (FDA) issued the Prescription Drug Marketing Act of 1987 (PDMA) which was then modified by the Prescription Drug Amendments of 1992. Included was Section 503(e)(1)(A) which establishes the pedigree requirement for prescription drugs.

A drug pedigree is a statement of origin that identifies each prior sale, purchase or trade of a drug, including the date of those transactions and the names and addresses of all parties involved.

In 2006 the FDA's Counterfeit Drug Task Force issued a report stating, "Widespread use of electronic track-and-trace technology would help secure the integrity of the drug supply chain by providing an accurate drug pedigree, which is a record of the chain of custody of the product as it moves through the supply chain from manufacturer to pharmacy."

The FDA issued its Guidance for Industry Standards for Securing the Drug Supply Chain—Standardized Numerical Identification for Prescription Drug Packages in March 2010, recommending package-level standardized numerical identifiers as "an initial step in FDA's development and implementation of additional measures to secure the drug supply chain."

The Drug Quality and Security Act (DQSA) of 2013 was signed into law on November 27, 2013. Title II of the DQSA is the Drug Supply Chain Security Act (DSCSA) which outlines steps to develop an electronic system to identify and trace pharmaceutical products throughout the supply chain in the USA. The first major "Deadline" facing drug manufacturers due to this new regulation is November 27, 2017, at which time a unique serial number must be applied to all drug packages and cases shipped into the U.S. market. The DSCSA requires the pharmaceutical industry to exchange information at the individual package level as products travel through the supply chain by November 27, 2023.



Complying with the DQSA will be a major undertaking since it will require changes in operating procedures for all personnel and organizations involved in getting drug products from the manufacturer to the end user. The goal of the legislation is to verify the authenticity of drug product identifier at the package level, while enabling counterfeit, potentially dangerous, products to be reliably and efficiently detected and removed from the supply chain.

Track and Trace and Serialization regulations are being implemented in the European Union, Brazil, Turkey, South Korea, China, India, Argentina, Jordan, Libya, Saudi Arabia, Slovenia, Ukraine, and several countries in Africa. Although each country's goal is to protect the integrity of the drug supply chain, they have requirements and deadlines that differ from those of the USA.



### **Will the industry be ready?**

A 2011 survey of representatives from 42 pharmaceutical firms by PharmTech, Inc., Libertyville, Illinois, indicated that only 18% were currently involved in serialization pilots. Participants were asked to estimate the implementation time for companywide serialization. Sixty percent of respondents expected the timeline to be one year or less. However, PharmTech estimates that it can take as long as three to five years, depending on the number of lines and products involved.

The industry must be ready to meet the DQSA deadlines since the regulation provides no alternatives other than compliance. The challenge is interpreting the regulation, determining how best to comply, and working with partners to develop and implement policies, procedures, and technology in a timely manner.

### **Pharmaceutical industry overview**

Before we get into specifics it's important to review some key pharmaceutical industry data points. These details are designed to give you a better understanding of the factors driving the serialization initiatives.

According to IMS Health, the global revenue for pharmaceutical products was projected to reach \$880 billion in 2011. The United States accounts for 36 percent of that business, with Canada coming in at 2.4 percent. A leading pharmaceutical media website, Pharmpro.com, estimates there are more than 25,000 packaging lines worldwide. Additional factors include:

- Up to 15% of all medicinal products in the world are counterfeit (*World Health Organization estimate*)
- Global sale of counterfeit drugs projected at \$75 billion in 2010 (*Center for Medicines in the Public Interest estimate*)
- 92% increase in counterfeit drugs 2005-2010 (*Center for Medicines in the Public Interest estimate*)



In addition to counterfeiting issues, drug cargo theft is also on the rise, ranging from truck hijackings to elaborate pharmaceutical warehouse break-ins. For example, in 2010, an Eli Lilly warehouse break-in was responsible for the loss of \$75 million in prescription pharmaceuticals.

Stolen pharmaceuticals frequently end up in developing countries or distributed via illegal online channels. As a result, quality, transport conditions, efficacy and other aspects are frequently compromised.

For example, in February 2012, counterfeit versions of Roche's cancer drug Avastin were found in Europe and the United States. After testing, the product was determined to only contain salt, starch and a variety of chemicals—none of which were part of Avastin's actual formulation. The counterfeit product was traced back to Egypt, entering the United States after passing through legitimate distributors in Switzerland, Denmark and the United Kingdom.

These illegal activities, coupled with standard pharmaceutical recalls, highlight the importance of having a system in place that can accurately and quickly monitor the entire pharmaceutical supply chain.

### **Serialization or 'track and trace' defined**

There are the three basic components of track and trace.

#### **Code printing**

- Alphanumeric (human readable, such as date and lot code), and/or
- Bar code (machine readable, such as Data Matrix 2D code)

#### **Code verification**

- Bar code reader/vision system

### **Serialization**

- Each individual drug package component (blister, bottle, carton, case, pallet, etc.) is marked with unique identifying code.
- Codes must be unique, random and unduplicated.
- Creation of a central database which allows manufacturers to track and store the location and status of each product as it travels through the supply chain until it is sold to the customer.

The unique identifier code needs to be applied and verified in multiple places along the production line. Examples include individual blisters, bottles, folding cartons, shipping cases and pallets.

With space always a premium on the production floor, pharmaceutical plant managers have to figure out ways to implement serialization without compromising square footage and productivity. The implementation strategy also has to be cost-effective.

### **Combining checkweighing with coding and verification**

Virtually all pharmaceutical production and repackaging lines employ a checkweigher, an automated scale designed to provide a very high level of weighing accuracy and repeatability. Checkweighers are typically located on packaging lines after bottle, blister or carton filling equipment, and at the end of the line to confirm case weights.

Integrating marking and verification equipment, the key elements of a track and trace / serialization / ePedigree solution—with a checkweigher, can save both cost and valuable floor space. Also, a checkweigher provides a means of automatically tracking products from the point of code verification to a reject mechanism. This provides the opportunity to have reject verification and fail-safe reject operation included in the system, both of which are of critical importance for most pharma applications.

A checkweigher designed specifically for pharmaceutical applications, and which complies with the industry's GMPs, has the ability to provide the highest level of weighing accuracy. This will serve as a good foundation for an integrated track and trace system. Another consideration is the system's operating speed. A system that will satisfy today's requirements, as well as having the capability to meet higher future speed requirements, is ideal.

When considering these multi-function checkweighers, here are some considerations to keep in mind.

#### **Motor type**

Ensure that the checkweigher's motor type and mounting location minimizes vibration, which improves checkweigher accuracy. (A single brushless motor mounted in the back of an enclosed cabinet is well suited for powering infeed, weigh table and outfeed conveyors.)

#### **Conveyor belt design**

Look for checkweigher designs which provide superior product handling from the infeed conveyor onto the weigh table at high speeds. (A "knife-edge" design provides smooth transition, which also improves accuracy.)

Additionally, side belts with horizontal and vertical adjustment ensure the correct position of the bottle or carton during marking and verification.

#### **Equipment flexibility**

Some checkweigher manufacturers have teamed up with specific code printing and verification equipment suppliers, while others offer complete flexibility regarding which components can be integrated into the system. The flexibility to choose the precise components that are right for your operation is generally preferred.

## Code printers

There are a variety of printers that can be used for track and trace / serialization purposes, including thermal, ink jet, laser, flexographic and drop-on-demand. The printer choice will typically depend on factors such as code printing location (a printer for a bottle may not be well suited for a pallet), information type, speed requirements, the material to which the code will be applied, cost of ownership, ease of use and print quality.

Printers typically are expected to apply both machine–and human readable codes. They must have a high level of accuracy and reliability so that codes are correct and legible throughout the supply chain.

## Verification systems

Verification systems are typically capable of reading and verifying both machine readable bar codes, Data Matrix (2D) codes and human-readable alphanumeric information. Bar code readers are being used in some instances, while smart cameras, that can include optics, lighting, embedded CPU, digital I/O, serial communications and Ethernet networking capabilities, are becoming more common.

## Operator interface

Another key differentiator in all-in-one systems is the operator interface. Some equipment manufacturers mount separate user interfaces for the checkweigher, code printer and machine vision system. Others incorporate control of all functions into one screen. (The latter significantly improves ease of operation and saves valuable line space.)

## Reject mechanisms

Combination checkweigher units should also feature two reject mechanisms—one for packages rejected by the vision system due to illegible or incorrect codes and the other for over/under weights. Reject verification, (making certain defective product was removed from the packaging line), and fail-safe operation, (assuming all packages are defective until proven good) are key features required for most pharma applications.

## Conclusion

With more than 25,000 pharmaceutical packaging lines worldwide, it is critical for companies that have not yet conducted a serialization or traceability readiness assessment to begin immediately.

With as long as five years estimated as the implementation timetable for some operations, many companies run the risk of not being ready by the time compliance is mandated.

As part of the research phase for your specific operation, partner with production line equipment manufacturers to find solutions best suited to your operations.

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